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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,924	04/20/2004	Holly Hurlbut Hogrefe	04121.0161-02000	5896

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EXAMINER	
HUTSON, RICHARD G	
ART UNIT	**PAPER NUMBER**
1652	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/828,924	HOGREFE ET AL.	
	Examiner	Art Unit	
	Richard G. Hutson	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,7-14,23-25 and 57-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-3,7-14,23-25 and 57-59* is/are allowed.

6)☒ Claim(s) *57-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment of claims 12-14, in the paper of 12/13/2006, is acknowledged. Claims 1-3, 7-14, 23-25 and 57-59 are at issue and are present for examination.

Applicants' arguments filed on 12/13/2006, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 57-59 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection was originally stated in the previous office action as it applied to previous claims 57-59. In response to this rejection, applicants have not amended the claims but rather traverse the rejection as it was applied previously to claims 57-59.

Applicants traverse this rejection on the basis that contrary to the previous assertion that "there is no disclosure of any particular structure to function/activity relationship in the single species", applicants assert that such a disclosure is

unnecessary to satisfy the written description requirement in this case. Applicants submit when a claim recites only functional characteristics, that claim may still be adequately described when those functional characteristics are coupled with a known or disclosed correlation between function and structure. In supporting this position applicants reference Example 16 of the "Synopsis of Application of Written Description Guidelines" and conclude that a known correlation between structure and function supports a finding of adequate written description for a claim that recites only function. Applicants further submit that nowhere does the MPEP state that a known correlation between function and structure is required where a claim recites both specific structure and function.

Applicants submit that the present claims recite both specific structure and function . Applicants submit that first the claimed polynucleotides comprise specific structure, that is a polynucleotide encoding an amino acid sequence possessing 95% identity to SEQ ID NO: 66. Applicants submit that second the claimed polynucleotides have a specific function, that is they encode an "archaeal replication factor A". Applicants further submit that an archaeal replication factor A has certain functions and activities that can enhance a polymerization reaction.

Applicants assert that the instant claims are more like Example 9 (rather than Example 16) of the Synopsis because the present claims recite both specific structure and function and nowhere in the analysis of Example 9 does the office rely on any known or disclosed correlation between structure and function in finding that the hypothetical claim is adequately described.

Finally applicants submit a copy of the nonprecedential decision of the Board of Patent of Appeals and Interferences, to support applicants position that a known or disclosed correlation between structure and function is not required for a finding of adequate written description of a claim that recites both structure and function.

Applicant's complete argument is acknowledged and has been carefully considered, however, is not found persuasive for the reasons previously stated and repeated herein.

Applicant's submission that the present claims recite both specific structure and function, is not persuasive. While it is recognized that the rejected claim recites structure (i.e. encoding a polypeptide comprising SEQ ID NO: 66, or possessing 95% identity to SEQ ID NO: 66), the rejected claims do not require a specific function. It is the function part of applicant's argument that is flawed. Applicants submit that claimed polynucleotides have a specific function, that is they encode an "archaeal replication factor A", is not persuasive because encoding an "archaeal replication factor A" is not considered a specific function. It is understood that an "archaeal replication factor A" may have many related and unrelated "functions". These include but are not limited to immunological function, such as acting as an antigen for an antibody; regulatory function, such as that exhibited by many proteins which control transcription and/or translation of not only their encoding nucleic acids but other nucleic acids as well; or enzymatic function. Thus as it is not clear what is encompassed by the "specific function" of an "archaeal replication factor A", it remains that applicants have not adequately described the claimed genus.

Thus the specification fails to describe additional representative species of these polynucleotides by any identifying structural characteristics or properties other than that recited in claim 57, for which no predictability of function is apparent. It is remains unclear what, if any functions are associated with the encoded "archael replication factor A" proteins of the claimed polynucleotides. Given this lack of additional representative species as encompassed by the claims and an associated description, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 57 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide encoding the archael replication factor A of SEQ ID NO: 66 or an isolated host cell transformed with a vector comprising said polynucleotide, does not reasonably provide enablement for any polynucleotide encoding the archael replication factor A having 95% identity to SEQ ID NO: 66 or a host cell transformed with said polynucleotide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

This rejection was originally stated in the previous office action as it applied to previous claims 12, 14 and 57. In response to this rejection , applicants have amended claims 12 and 14 and traverse the rejection as it was applied previously to the newly amended claims. The rejection of claims 12 and 14 have been withdrawn based upon applicants amendment of these claims.

Applicants traverse this rejection on the basis that "The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue".

Applicants submit that previously two contradictory positions have been taken in making the rejection. Applicants submit, on the one hand, that the examiner alleged that "the claims ... do not place any functional limits on the enzymes encoded by the claimed polynucleotides." And on the other hand, the Examiner goes on to allege that the claims are not enabled because the specification does not provide "a rational and predictable scheme for modifying any amino acid residue of any protein having a similar function as SEQ ID NO: 66 with an expectation of obtaining the desired biological function..." Applicants submit that "the claim either possess functional elements or it does not." Applicants submit that for the reasons cited above in response to the written description rejection, applicants assert the claimed polynucleotides have a specific function (i.e. an archael replication factor A).

In response to applicants initial comments regarding the current rejection, for the reasons stated above, in response to applicants response to the written description rejection it is submitted that the rejected claims do not have a "specific function", as

encoding an "archael replication factor A", is not a specific function. Thus as previously stated "no functional limits are placed on the enzymes encoded by the claimed polynucleotides." Further such a conclusion is not contradictory to the also previously made statement that the claims are not enabled because the specification does not provide "a rational and predictable scheme for modifying any amino acid residue of any protein having a similar function as SEQ ID NO: 66 with an expectation of obtaining the desired biological function..." It is not questioned that the protein comprising SEQ ID NO: 66 has a function, it is just that any such function whatever it may be, is not necessarily a specific function and any such function is clearly not a limitation of the rejected claims. As above, it is understood that an "archaeal replication factor A" may have many related and unrelated "functions". These include but are not limited to immunological function, such as acting as an antigen for an antibody; regulatory function, such as that exhibited by many proteins which control transcription and/or translation of not only their encoding nucleic acids but other nucleic acids as well; or enzymatic function. Thus as it is not clear what is encompassed by the "specific function" of an "archaeal replication factor A", it remains that applicants have not enabled the claimed genus.

Applicants further traverse the rejection on the basis that contrary to the previous assertion, based upon the reference Ngo, one of skill in the art would not be trying to determine the structure of a given protein from its amino acid sequence alone, but rather one would be trying to determine whether a particular amino acid change in an

amino acid sequence would cause the protein encoded by that amino acid sequence to cease function as an RFA. Applicants assert that these are two different inquires.

As an initial response to applicants comment that "one of skill in the art would not be trying to determine the structure of a given protein from its amino acid sequence alone, but rather one would be trying to determine whether a particular amino acid change in an amino acid sequence would cause the protein encoded by that amino acid sequence to cease function as an RFA", it continues to be questioned as to what function it is that applicants are referring to. As discussed above and previously while an "archaeal replication factor A" may have many functions, it is not itself a specific function.

Finally applicants argue that even if one skilled in the art could not have predicted whether a particular amino acid change would cause an RFA to cease to function, applicants have provided extensive guidance and two separate assays which can be used to screen an RFA for function. In response to applicants arguments regarding the screening for an RFA function, while applicants may provide two assays used to screen for a characteristic or function of an RFA, it remains that the specific function of an RFA protein, continually eluded to by applicants is unclear, and it remains that applicants have not enabled the extensive genus of functions encompassed by all those functions of any RFA protein.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any polynucleotide encoding an archael

replication factor A having 95% identity to SEQ ID NO: 66. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of those polynucleotides having the desired biological characteristics continues to be unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Conclusion

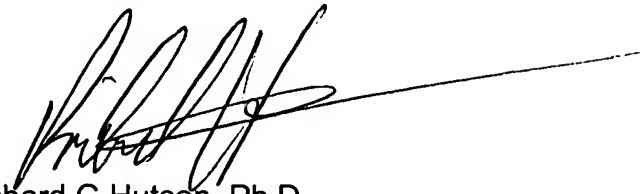
THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is 571-272-0930. The examiner can normally be reached on M-F, 7:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Richard G Hutson, Ph.D.
Primary Examiner
Art Unit 1652

rgh
3/7/2007